

REMARKS

In the amendments above, Claim 2 and 44 have been amended, and new Claims 60 to 78 have been added, to more particularly point out and distinctly claim Applicants' invention. Certain amendments have been made to the specification to correct obvious inadvertent errors, particularly with regard to correspondence with the drawings. Attached hereto are two sheets of replacement drawings where Figures 6, 18, and 20 have been amended to correct inadvertent numbering errors and to conform to the specification. Also attached are two sheets of the earlier drawings where changes are indicated.

Claim 11 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner maintains that Claim 11 includes the limitation "irregular shape" and that it is unclear what an irregular shape, or a regular shape, would entail.

Applicants respectfully traverse the above rejection. Applicants believe that one skilled in the art would appreciate the meaning of "irregular" in the context of the instant disclosure. See, for example, paragraphs 93 to 118 and Figures 10 to 15. In addition, the Examiner's attention is directed to any conventional dictionary, such as the Tenth Edition of *Merriam Webster's Collegiate Dictionary*, copies of pages 619 and 620 of which are attached hereto. One of the definitions of "irregular" is " ... lacking perfect symmetry or evenness "

Since one skilled in the art would certainly appreciate the language of Claim 11, the rejection of Claim 11 under §112, second paragraph, should be withdrawn.

Claims 2-12 have been rejected under 35 U.S.C. §102(b) as being anticipated by Reich et al., U.S. Patent No. 5,962,620 ("Reich"). The Examiner maintains that Reich discloses hydrophilic and hydrophobic polyester polyurethanes; that Reich also discloses that the polyurethanes may be used to form a shape structure or device including tubing, catheters, stents, and the like; that Reich also discloses that hydrophilic polymers may include drugs and enzymes, and may be coated over the polyurethanes; that Reich further discloses encapsulation of drugs in preferably, high viscosity hydrophilic polymers; and that the disclosures of Reich anticipate the claims.

Applicants respectfully traverse the rejection based upon §102.

The invention described and claimed herein is directed to an implant for delivering therapeutic agents, which implant comprises a resilient or flexible elastomeric scaffold having a coating. It is noteworthy that the scaffold is reticulated, i.e., it comprises interconnected or intercommunicating voids or pores. Moreover, the scaffold is at least partially hydrophobic, and the coating contains one or more therapeutic agents to be released within a patient.

As the Examiner pointed out, Reich discloses hydrophilic or hydrophobic polyester polyurethane substrates that may optionally have a coating. However, Reich's substrates are either solid or liquid (see, for example, Column 3, lines 45-46, Column 4, lines 5-14 and 59-61, and Column 5, lines 49-50), not the resilient or flexible reticulated substrates required according to Applicants' invention.

As support for the §102 rejection the Examiner referenced Column 3, lines 38-43, and Column 15, lines 7-8, of Reich. In these passages Reich discloses either that an amphiphilic coating is coated over a substrate, optionally with a biocompatible hydrophilic coating, or that a hydrophobic coating and a hydrophilic coating are coated over a polymeric or even non-polymeric substrate. There is no disclosure or suggestion

that a coating, preferably hydrophilic, is to be applied over a resilient or flexible, at least partially hydrophobic, reticulated elastomeric support scaffold.

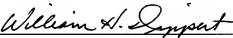
The Examiner's attention is directed to Claim 2 above, where "comprising" has been replaced by the terminology "consisting essentially of," to emphasize the distinctions over Reich.

Applicants submit that the claims herein, including the newly added claims and the withdrawn claims, are patentable over Reich. Therefore, the rejection under §102 should be withdrawn.

Reconsideration and allowance of all the claims herein are respectfully requested.

Respectfully submitted,

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